

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraphs in the specification with the following amended paragraphs:

[0027] In an alternative embodiment, the present invention provides a medium that functions as a reagent disc 48 for loading of a reactant system. Preferably, in this embodiment, the polymeric material has a density of about 0.05 g/cc; an average pore size of from 0.9 to 1 mm; a pore size range of about 0.2 mm to about 1.2 mm; and an absorptive capacity of approximately 15 g of water/g of polymeric material. One aspect of this embodiment provides for loading the reactant mixture onto the reagent ~~reactant~~ disc 48 by contacting a solution of the reactant mixture in an appropriate solvent onto the polymeric material of which the reagent disc 48 is comprised and removing the solvent from the polymeric material.

[0050] Also illustrated in FIG. 2 are additional structural elements of which the sampling wand 17 is comprised. These include a reagent reservoir 23 located toward the distal end of the sampling wand 17. This reservoir is of approximately 200-250 μ L in total volume. As will be discussed in greater

detail below, the contents of this reservoir that, in one embodiment, comprise a buffered neutralizing solution, are released into the inner chamber (not illustrated) of the sampling/analysis member by piercing structures located within that inner chamber. The sampling wand 17 further comprises a polymeric sampling swab 27 disc 27 adhered to the exterior of the distal end of the sampling wand 17, and on a common vertical axis with the wand. Also illustrated in FIG. 2 is an o-ring structure 25 located toward the distal end of the wand 17, and situated on the exterior of the cylindrically shaped distal portion. The purpose of the o-ring 25 is to provide a sealing fit between the outer surface of the distal portion of the wand 17 and the inner surface of the inner chamber (not illustrated) of the sampling/analysis member 15, as the wand 17 moves longitudinally through the inner chamber. It is preferred to achieve such sealing fit between the wand 17 and the inner chamber in order to prevent the drying out of the pre-wetted sampling swab 27 17.

[0052] FIG. 4 illustrates the sampling/analysis member 15 of the device of the present invention in an exploded view. Part numbers are consistent with the part numbers referenced in FIGS. 1-3 for identical structural elements, a convention

adhered to throughout this description. Starting from the top, or proximal, end of the sampling/analysis member, there is shown a top 19 of the sampling wand 17. Toward the distal end of the sampling wand 17, there is shown the reservoir 23, and the o-ring channel 26. Immediately below the distal end of the sampling wand 17, there is shown the o-ring 25 that sits in the o-ring channel 26 to provide, as discussed above, a sealing fit between the sampling wand 17 and the inner walls of the inner chamber 40. Shown immediately below the o-ring is the upper seal 29 that sits on the lower edge/surface (not shown) of the distal end of the sampling wand 17. The seal 29 is made of a frangible material, preferably aluminum foil coated to improve chemical resistance, and is adhered through use of an appropriate adhesive to the bottom edge/surface of the sampling wand. The seal 29 serves to seal the reagent solution within the reservoir 23, and to prevent the diffusion of species from the reservoir across the membrane as would likely be the case with non-metallic seals. The next component illustrated in FIG. 4 is the polymeric sampling swab 27, the composition of which is discussed in more detail below. The sampling swab 27 is affixed to the bottom of the sampling wand 17, with the upper seal 29 interposed between it and the reagent reservoir 23.

[0062] Once the sampling wand ~~swab~~ 17 has been used to collect a sample from the surface onto the sampling swab 27, the sampling wand 17 is returned to the sampling/analysis member 15 where the wand is re-inserted into the inner chamber 40 of the sampling/analysis member. When first re-inserted, the sampling wand 17 can be returned to its original longitudinal position within the inner chamber 40 of the sampling/analysis member 15. In that position, the member 15 is in substantially the same arrangement as depicted in FIG. 5. In that arrangement, upper seal 29 remains undisturbed, and the contents of the reservoir 23 are intact.

[0080] Use of the polymeric material as a medium onto which to load the chemiluminescent reactants offers significant advantages over prior art methods. To begin with, as discussed briefly above, aqueous solutions of luciferin-luciferase at concentrations suitable for typical assay procedures are relatively unstable and cannot be used more than a day after preparation without significant loss of emission intensity, and then only after a recalibration of the emission signal as a function of ATP standard concentration. The recognized prior art solution to the

problems associated with instability of aqueous solutions of the reagents is to prepare the reagent mixture in a lyophilized, or freeze dried, form, which composition is then typically coated on the inner surfaces of a reaction vessel. Direct loading onto the durable polymeric material eliminates the need for the lyophilization step in the preparation of the reactants, and also provides for more readily achieved rehydration of the reagents once the reagent ~~reactant~~ disc 48 is in contact with the sample solution. This is due, in part, to the relatively large internal surface area of the preferred polymeric material (see Table 2, above) that provides for almost instantaneous mixing of the reservoir solution with the reagents in the reagent disc 48.

[0082] In an alternative embodiment of the present invention, the chemiluminescent reagent formulation loaded onto the reagent disc ~~reactant discs~~ 48 can be prepared with an additional ingredient that provides superior results in the chemiluminescent assay of the present invention. This additional reagent is trehalose, a common disaccharide.

[0087] In addition to the luciferase reactant system

disclosed above, it is possible for the device and methods of the present invention to be adapted to assays of additional analytes of interest. In order to achieve this, the reactant mixture would be modified to comprise an alternative enzyme to luciferase, where that enzyme would be capable of oxidizing a specific substrate of interest. Examples of such substrates for which specific enzymes are available would be sugars such as glucose and galactose; lipids such as fatty acids and cholesterol; amino acids and other amines; pyruvate; nicotine adenide dinucleotide (NAD) and derivatives; and alcohols. In general, the substrate of interest would be oxidized by the enzyme to generate hydrogen peroxide, H_2O_2 , as one of the reaction products. The peroxide, in turn, can react with the specific reactant system in the reagent ~~reactant~~ disc 48, and generate a luminescence signal detectable in the luminometer 20 of the present invention. Thus, by changing the reactant mixture loaded onto the reagent ~~reactant~~ disc 48, it is possible to adapt the device and methods of the present invention to assays for a wide range of analytes of interest.